

EXHIBIT E

1
2 IN THE UNITED STATES DISTRICT COURT
3 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
4 AT CHARLESTON
5

6
7 JO HUSKEY AND ALLEN HUSKEY, :
8 Plaintiffs, : CASE NUMBER
9 v. : 2:12-cv-05201
10 ETHICON, INC., ET AL., :
11 Defendants. :
12

13
14 TRANSCRIPT OF TRIAL - DAY TWO

15 AUGUST 25, 2014

16 BEFORE THE HONORABLE **JOSEPH R. GOODWIN**,
17 UNITED STATES DISTRICT JUDGE
18
19

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24 Proceedings recorded by machine stenography; transcript
25 produced by computer.

GUELCHER - CROSS - THOMAS

1 A. Prolene is a brand name, it's essentially polypropylene
2 with antioxidants and lubricants.

3 Q. And Ethicon first used Prolene in its sutures?

4 A. That's my understanding.

5 Q. And sutures are what we in West Virginia call stitches,
6 right?

7 A. Call them that in Virginia, too, where I grew up.

8 Q. Down in Blacksburg?

9 A. Yes, sir.

10 Q. And so Ethicon Prolene stitches or sutures have been
11 around since the late Sixties?

12 A. That's my understanding, they've been around since the
13 Sixties.

14 Q. And what makes Prolene Prolene as opposed to simple
15 polypropylene are the additives that you talked about,
16 correct?

17 A. Yes. The brand name Prolene is defined by the additives
18 that are added to the polypropylene.

19 Q. And those additives are calcium stearate, do you remember
20 that?

21 A. Calcium stearate is added as a lubricant.

22 Q. And DLTPD because I can't pronounce the full word.

23 A. It's a long word. It's an antioxidant.

24 Q. Santonox R?

25 A. Another antioxidant.

GUELCHER - CROSS - THOMAS

1 Q. Procol LA-10?

2 A. I think that's another surfactant.

3 Q. And a CPC --

4 THE COURT: That's another what? I didn't hear it.

5 THE WITNESS: I'm sorry. It's another surfactant or
6 a lubricant.

7 THE COURT: All right.

8 BY MR. THOMAS:

9 Q. And then the coloring, the CPC pigment, correct?

10 A. Yes, sir.

11 Q. And those additives are what make Prolene different from
12 the other polypropylene medical devices on the market,
13 correct?

14 A. There are many different grades of polypropylene; Marlex,
15 Prolene, different grades --

16 THE COURT: Is that a yes or a no?

17 THE WITNESS: I'm sorry. Yes.

18 MR. THOMAS: Thank you.

19 BY MR. THOMAS:

20 Q. Now, Ethicon Prolene sutures are what is known as
21 non-absorbable sutures, correct?

22 A. They're marketed as non-absorbable.

23 Q. Okay. And what that means is they are supposed to be in
24 the body for life?

25 A. They're supposed to be without changing, yes.

GUELCHER - CROSS - THOMAS

1 anything. But I have taught a course, developed a course on
2 polymer science and engineering at Vanderbilt, I taught it for
3 two semesters, other professors teach it now, and we talked
4 about many types of polymers in this course. So I am familiar
5 with polypropylene, but I do agree that I've not studied it in
6 my research. So it's just this word that I am struggling a
7 little bit with. If you asked me if I've done research, I
8 would say no, I have not, but I have studied and I am aware of
9 the material.

10 THE COURT: All right. Next question.

11 MR. THOMAS: Thank you, Your Honor.

12 BY MR. THOMAS:

13 Q. Now, you obviously know that Ethicon's TVT mesh is
14 designed to be implanted in the human body?

15 A. Yes, that's correct.

16 Q. And you know when those meshes are removed from the human
17 body then they're called an explant?

18 A. That's what I was explaining earlier.

19 Q. You have never analyzed a TVT mesh explant manufactured
20 by Ethicon for the treatment of stress urinary incontinence,
21 true?

22 A. I've not had any explant to --

23 Q. True?

24 A. -- characterize, so --

25 Q. I'm sorry. I don't mean to stop you, but --

GUELCHER - CROSS - THOMAS

1 THE COURT: I'll take that as an objection as
2 non-responsive. I'll sustain the objection and direct the
3 witness to answer the question as asked.

4 THE WITNESS: That's true, I've not tested it.

5 THE COURT: Can I see counsel at sidebar?

6 (The following occurred at sidebar.)

7 THE COURT: We're coming close or at least it seems
8 to me to discussing the other mesh cases. I want just to be
9 very sure we don't do that.

10 MR. THOMAS: I'm trying to tailor my questions to
11 Ethicon specifically, Your Honor.

12 MR. WALLACE: Just fair warning, he has looked at
13 mesh and you're about to open a can of worms.

14 THE COURT: He was specific that it was only Ethicon
15 and I'm worried about the witness --

16 MR. WALLACE: I'm not sure he completely gets where
17 he's going.

18 THE COURT: Are you going to ask more questions about
19 that, explant testimony?

20 MR. THOMAS: Just Ethicon specific.

21 THE COURT: Make it clear that you only want an
22 answer about Ethicon.

23 MR. THOMAS: Yes, sir.

24 THE COURT: Just this particular case.

25 (Sidebar concluded.)

—GUELCHER - CROSS - THOMAS—

1 Q. Now, if you go to the next slide in this set, you're
2 talking about the implant materials selection. This
3 polypropylene, does the polypropylene in this slide, is this
4 Prolene?

5 A. No, this isn't Prolene; this is polypropylene.

6 Q. Okay. And we talked about before that Prolene without
7 antioxidants?

8 A. That's not Prolene.

9 Q. Exactly.

10 A. It's polypropylene.

11 Q. And as you add antioxidants to it, you do so to stabilize
12 the polypropylene, correct?

13 A. To get the oxidation, yes.

14 Q. And the reason why you do that is to extend the life of
15 the polypropylene for whatever it's being used for, correct?

16 A. That's right, yes.

17 MR. THOMAS: May I approach, Your Honor?

18 THE COURT: You may.

19 BY MR. THOMAS:

20 Q. Now, Dr. Guelcher, I've handed you what's been marked as
21 defendants' exhibit 30884 and this is a 1976 study called
22 *Subcutaneous Implants of Polypropylene Filaments*, first author
23 Liebert, correct?

24 A. Yes.

25 Q. And you're familiar with this paper, aren't you?

—GUELCHER - CROSS - THOMAS—

1 A. I cited this paper in my report.

2 Q. And in the Liebert paper, the authors there tested
3 polypropylene without antioxidants against polypropylene with
4 antioxidants, correct?

5 A. They did, but they were different components, but they
6 did, yes.

7 Q. Thank you.

8 And if you go to page two of this exhibit, 3884.2, down
9 at the bottom it says, "The objectives of the study were
10 determined the length of time required for observable
11 degradation to occur, the type of degradation products formed,
12 the rate of degradation, and four, the effect of the presence
13 of an antioxidant on degradation and the rate of degradation."

14 Do you see that?

15 A. That's right. That's what it says.

16 Q. And what the Liebert article found was that there was no
17 oxidation of the polypropylene treated with antioxidants,
18 correct?

19 A. At 90 days they found that.

20 Q. Correct?

21 A. At 90 days, yes.

22 Q. And at paragraph five on the last page under conclusions,
23 the Liebert group concludes, "Infrared spectra and mechanical
24 testing of implanted and non-implanted filaments containing an
25 antioxidant show no changes in chemical or physical properties

GUELCHER - CROSS - THOMAS

1 A. Yes, I've published a lot of peer-reviewed studies.

2 Q. And a peer-reviewed study is one that somebody writes and
3 subjects to review by your peers before it's published,
4 correct?

5 A. That's how it works.

6 Q. And in the 50 years that Prolene polypropylene has been
7 used for implantation in humans, you're not aware of any
8 peer-reviewed study which suggests that Ethicon Prolene loses
9 its antioxidant package such that it oxidizes and becomes
10 embrittled, are you?

11 A. I've not seen that in a peer-reviewed study.

12 Q. You don't have an opinion in this case about whether Mrs.
13 Huskey's mesh degraded, do you?

14 A. I believe it degraded based on the foreign body reaction,
15 but I don't have the data, is that fair?

16 Q. You don't know whether the mesh is brittle, do you?

17 A. I've not tested it.

18 Q. You don't know whether it's oxidized at all, do you?

19 A. As I said, I believe it is, but I've not tested it
20 because I don't have it.

21 Q. That's because you don't have the material to test,
22 correct?

23 A. Yes, sir, that's right.

24 Q. Let's go to page 10 of the Power Point presentation,
25 please.

GUELCHER - CROSS - THOMAS

1 Now, you talked to the jury at some length about this
2 flow chart, the effect of the foreign body reaction on
3 implants, and just so it's clear, what you depict here is not
4 your experience with polypropylene, correct?

5 A. What I show here is based on the experience with the
6 pacemaker lead insulation and what I believe is happening to
7 polypropylene.

8 MR. THOMAS: Your Honor, move to strike. Ask him to
9 answer the question.

10 THE COURT: Sustained. The witness is directed to
11 answer the question.

12 THE WITNESS: Okay. Sorry. What's the question
13 again?

14 BY MR. THOMAS:

15 Q. Dr. Guelcher, what you showed here is not related to your
16 experience with polypropylene?

17 A. Not my experience.

18 Q. What you show here is your experience with polyether
19 urethane, correct?

20 A. It's not my experience. It's published experience, yes.

21 Q. You've not done this analysis, testing it, analyzing it,
22 published it, with respect to polypropylene, have you?

23 A. No. But I'm in the process of doing that. I'm sorry.

24 MR. THOMAS: Your Honor, move to strike.

25 THE COURT: Sustained.

GUELCHER - CROSS - THOMAS

1 THE WITNESS: I have not done it yet.

2 BY MR. THOMAS:

3 Q. Now, you talked about the seven-year dog study. There
4 was no evidence of embrittlement in the sutures tested in the
5 seven-year dog study, do you agree with that?

6 A. Yes, there was no embrittlement reported in that study.

7 Q. Thank you.

8 A. Well, can I qualify it?

9 Q. And there was no evidence of mechanical breakage in the
10 seven-year dog study, correct?

11 A. I believe on the surface there was evidence of
12 embrittlement, but what you've asked me --

13 Q. There's no evidence of mechanical breakage in the
14 seven-year dog study?

15 A. I do agree that there's no evidence of mechanical
16 breakage.

17 Q. And no evidence of loss of the mechanical properties of
18 the sutures in the seven-year dog study, do you agree with
19 that?

20 A. Can I be specific? There was tensile strength,
21 elongation and modulus, and those parameters were not changed.
22 Well, they were changing, but --

23 THE COURT: Can you answer the question?

24 A. Those three prongs.

25 Q. Thank you.

GUELCHER - CROSS - THOMAS

1 MR. THOMAS: May I approach, Your Honor?

2 THE COURT: You may.

3 BY MR. THOMAS:

4 Q. Dr. Guelcher, I'm handing you what's been marked as
5 defendants' exhibit 23228.

6 A. Yes.

7 Q. And 23228 is entitled, *Seven-Year Dog Study*.

8 A. Yes, I've seen this.

9 Q. It's a bigger version of what you talked about on direct?

10 A. Yes, sir.

11 Q. Has more information than what we talked about on your
12 direct examination, do you realize that?

13 A. Yes. I've seen the entire study.

14 Q. And the last three pages of that study are the mechanical
15 properties testing conducted on the mesh after seven years,
16 correct?

17 A. Yes.

18 Q. And it's this testing after seven years that showed that
19 the mesh explanted from the dogs after seven years did not
20 lose any of its physical properties, correct?

21 A. I would not say it does not lose any of its physical
22 properties. They measured strength, elongation and modulus.

23 Q. For what they tested they didn't lose any of their
24 physical properties, correct?

25 A. For what they tested.

GUELCHER - CROSS - THOMAS

1 Q. Is that true?

2 A. Yes.

3 Q. Thank you.

4 And also, if you go to page 115 -- are you at 115?

5 A. I'm at 115.

6 Q. Okay. Turn the page briefly. 116 is the area where you
7 testified to the jury about the conclusions, correct?

8 A. That's right.

9 Q. And it's conclusions under optical microscopy and
10 scanning electron microscopy, correct?

11 A. Right.

12 Q. And those would be visual observations of the test,
13 correct?

14 A. Well, it's scanning -- it's high magnification, it's
15 visual.

16 Q. It is visual, correct?

17 A. It is visual of the surface, yes.

18 Q. Well, Ethicon also conducted some analytical chemistry on
19 the mesh they explanted from the dogs too, didn't they?

20 A. They it.

21 Q. And if you go to page 115, they talk about GPC testing,
22 correct?

23 A. Yes.

24 Q. GPC testing is gel permeation chromatography, correct?

25 A. That's what it stands for.

—GUELCHER - CROSS - THOMAS—

1 Q. And gel permeation chromatography measures molecular
2 weight, right?

3 A. That's right, measures molecular weight.

4 Q. And what the company found when it measured the molecular
5 weight after of these sutures after 17 years is that there was
6 no significant difference in molecular weight, correct?

7 A. A couples things. Not 17 years, seven years.

8 Q. I misspoke. Let me ask the question again so it's clear.
9 Isn't it true that the company reported on October 15, 1992
10 that the results of the gel permeation chromatography test run
11 on Prolene sutures explanted from dogs after seven years
12 showed no significant difference in molecular weight, correct?

13 A. That's the way they explain it, but there's not much
14 difference that's given there.

15 Q. Thank you.

16 Do you have the Wood article in front of you?

17 A. Yes, sir, I've got it right here.

18 Q. Wood?

19 A. Wood.

20 Q. The Wood article addressed hernia meshes, correct?

21 A. Yes, sir.

22 Q. It doesn't address Prolene polypropylene, does it?

23 A. It doesn't say Prolene, it says polypropylene.

24 Q. Okay. The Costello article.

25 A. Yes.

GUELCHER - CROSS - THOMAS

1 Q. I'm sorry, I don't have the number in front of me. Do
2 you have the number?

3 A. Yes. It's 21468.

4 Q. The Costello article to which you referred on direct, if
5 you go to page two, that's a different mesh company
6 altogether, isn't it? It's a Bard mesh, see under materials
7 and methods?

8 A. It's a Bard mesh with a polypropylene component.

9 Q. Okay. But it's not Prolene polypropylene, is it?

10 A. It's not Prolene.

11 Q. Now, let's go to the Clavé article. Would you bring that
12 up, please? It's 21457.

13 If you go to the sixth page of that, under discussion?

14 A. Yes.

15 Q. Just the first paragraph under discussion, please.

16 A. I'm looking for it.

17 Q. It says, "The primary objectives of this study were to
18 objectively observe a series of prosthetic explants and to
19 characterize potential degradation which may occur in vivo."
20 Correct?

21 A. That's what it says.

22 Q. Those are the goals. And they did it by a number of
23 analytical chemistry tests, correct?

24 A. Yes.

25 Q. And if you go to the bottom right-hand corner of that

—GUELCHER - CROSS - THOMAS—

1 same page, under several hypotheses, last paragraph? Can we
2 blow that up for the jury, please?

3 "Several hypotheses concerning the degradation of the
4 polypropylene are described below. None of these,
5 particularly direct oxidation, could be confirmed in this
6 study."

7 Did I read that correctly?

8 A. You read that correctly. That's the author's opinion.

9 Q. They're the ones that did the study, correct?

10 A. That doesn't mean I agree with that statement.

11 Q. Well, you've not done this study, have you?

12 A. No, but it's common to see papers --

13 Q. Okay. Thank you.

14 THE COURT: I cautioned you about argument. Let's
15 just stop arguing.

16 THE WITNESS: Okay. Sorry.

17 BY MR. THOMAS:

18 Q. Next page, please.

19 Under direct oxidation of the polypropylene, last
20 sentence.

21 A. Yes.

22 Q. FTIR is an analytical chemistry technique where you
23 determine the extent to which there's oxidation in
24 polypropylene, correct?

25 A. I spoke about that in my direct, yes.

(A recess was taken at 5:03 p.m.)

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REPORTERS' CERTIFICATE

Carol Farrell, CRR, RMR, CCP, RPR, Official Court
Reporter of the United States District Court for the Southern
District of West Virginia, and **Anthony Rolland, CRR, RMR, RPR**,
do hereby certify that the foregoing is a true and accurate
transcript, to the best of our ability, of the proceedings as
taken stenographically by and before us at the time, place,
and on the date hereinbefore set forth.

/S/ Carol Farrell, CRR, RMR, CCP, RPR

08/25/2014

Court Reporter

Date

/S/ Anthony Rolland, CRR, RMR, RPR

08/25/2014

Court Reporter

Date